K061227
Page 1 of 2

510(k) Summary

Summary Information: Amended November 14, 2006 as per FDA communications dated June 9, 2006 and November 7, 2006.

- Submitters Name and Address: The Hymed Group Corporation
  1890 Bucknell Drive
  Bethlehem, PA 18015

DEC 20 2006

- Contact Person: Dr. George Petito
  President
  Phone: 610-865-9876
  E-Mail: apetito@hymed.com

- Establishment Number: 2530949

- User Fee ID Number: MD6025566-956733

- Date of Amended Summary Preparation: November 14 2006

- Name of Device:

  - Proprietary: Hydrolyzed Collagen/Ag Wound Gel
  - Common: Moist wound gel
  - Classification Name: Hydrophilic Wound Dressing

- Medical Device Classification: Unclassified, PMN Non-exempt
  ProCode - FRO

- Identification of predicate devices to which substantial equivalence is being claimed:

  - HyCure® Hydrolyzed Collagen K955506
  - HeliDerm™ Collagen Wound Dressing K990086
  - X-Static® Silverseal Hydrogel Wound Dressing K040019
  - SilvaSorb Silver Antimicrobial Wound Gel K011994
  - AcryDerm Silver Antimicrobial Wound Dressing K011994

- Description of the Device: Hydrolyzed Collagen/Ag Wound Gel is a line extension of the previously approved HyCure® Hydrolyzed Collagen (K955506). Collagen/Ag gel is the identical hydrolyzed collagen wound gel formulation with 1.0% silver oxide added to inhibit the growth of

microbes that are absorbed into the wound gel. The addition of silver oxide to the HyCure® formulation does not affect the safety or efficacy of Collagen/Ag gel. HyCure® Hydrolyzed Collagen Wound Gel contains a high concentration of water bound to the hydrolyzed collagen which maintains a moist wound environment as it manages wound healing. Collagen/Ag Wound gel is provided in a patient ready dispensible tube.

- Intended use of the Device: Collagen/Ag Wound Gel is an absorbent wound dressing that provides a moist wound environment and affects the proliferation of bacteria which have been absorbed into the wound gel. Collagen/Ag gel is useful in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites.

- Technology Characteristics: Collagen/Ag Wound Gel is an aqueous, hydrogel identical in formulation to HyCure® Hydrolyzed Collagen Wound Gel (K955506). Collagen/Ag Wound Gel contains 1.0% silver oxide for the purpose of controlling bacterial bioburden within the gel as does silver containing hydrogels currently in commercial distribution and the particular change does not affect the intended use or alter the fundamental scientific technology of the device.

- Non-Clinical Performance Data: Hydrolyzed Collagen/Ag Wound Gel has been evaluated in accordance with Part 10-993 of the International Standard Organization (ISO). Standard tests which include:

    - cytotoxicity (Exhibit I) indicated a grade 1 cytotoxic grade,
    - Microbial control within the hydrogel claims are supported by *in-vitro* evaluation (Exhibit II). Collagen/Ag gel was found to control bacterial growth within the hydrogel.

Collagen/Ag gel has not been studied in a clinical setting.

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Hymed Group Corporation
% George Petito, Ph.D.
President
1890 Bucknell Drive
Bethlehem, Pennsylvania 18015

DEC 20 2006

Re: K061227
Trade/Device Name: Hydrolyzed Collagen Gel with Siver
Regulation Class: Unclassified
Product Code: FRO
Dated: November 14, 2006
Received: November 20, 2006

Dear Dr. Petito:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K061227

Device Name: Hydrolyzed Collagen Gel with Silver
Indications For Use:

Pressure ulcers (Stages I – IV)
Venous stasis ulcers
Diabetic ulcers
Ulcers resulting from arterial insufficiency
Surgical wounds
Traumatic wounds
First and second degree burns
Superficial wounds
Grafted wounds and donor sites

Prescription Use X AND/OR Over-The-Counter Use __
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061227